## REMARKS

Claims 1-4, 7, 8, 11-20 and 52 are currently pending in this application. Applicants respectfully request reconsideration of pending claims 1-4, 7, 8, 11-20 and 52. Claims 1, 12, and 19 have been amended, and new claims 53-55 have been added. No new matter has been added by way of this amendment, and support for each of the new and amended claims can be found throughout the specification, *e.g.*, at page 7, lines 1-8.

After entry of this amendment, claims 1-4, 7, 8, 11-20 and 52-55 will be pending. Applicants respectfully request reconsideration of pending claims 1-4, 7, 8, 11-20 and 52-55.

### I. Double Patenting Rejections

Claims 1-4, 7, 8, 11-20 and 52 have been rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent Nos. 6,335,028 ("the '028 patent") (claims 1-21), 6,660,301 ("the '301 patent") (claims 1-53), and 6,790,456 ("the '456 patent") (claims 1-44) (Office Action dated September 19, 2005, pages 2-3).

Applicants respectfully traverse this ground of rejection. For completeness, each ground of rejection will be addressed individually below.

#### A. U.S. Patent No. 6,335,028

The claims of the '028 patent recite a method for treating urinary incontinence; whereas the claims of the present invention recite compositions for tissue bulking. The Examiner opines that it would have been obvious to make a composition as presently claimed and use it in the claimed methods of the '028 patent (Office Action dated September 19, 2005, pages 2-3).

The Manual of Patent Examination Procedure (M.P.E.P.) describes the requirements for an obviousness-type double patenting rejection:

> Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent,... when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d *1869 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

M.P.E.P. § 804-II-B (Emphasis in original).

Applicant respectfully point out that the Examiner has previously restricted claims in the present case to 3 "distinct" groups: Group I drawn to compositions (claims 1-20), Group II drawn to methods (claims 21-46), and Group III drawn to kits (claims 47-51) (Office Action dated June 18, 2002). While Applicants traversed this rejection (Reply dated December 19, 2002), the Examiner maintained the Restriction Requirement, stating that "a kit is not related to a composition or a method, and the search of a method of use does not encompass a search for a compositions with specific constituents" (Office Action dated February 12, 2003, page 2).

Thus, by the Examiner's reasoning, claims directed to a method of using a composition are patentably distinct from claims directed to a composition.

Moreover, the claims of the '028 patent generally recite "flexible" microparticles. With respect to the term "flexible," the '028 patent specification states:

> The elastic microspheres for use in the present invention are flexible so that they can easily pass into and through injection devices without being broken or permanently altered in shape, but the microparticles are also resistant to the muscle contraction stress generated during and after the implantation process.

('028 patent, Col. 6, lines 44-49) (emphasis added). In contrast, the claims of the present application recite "swellable" microspheres comprising a "high water absorbing polymer." As those skilled in the art are aware, not all "flexible" microparticles are "swellable" or comprise a

"high water absorbing polymer," as recited in independent claim 1.

None of the claims of the '028 patent recite *any* composition comprising swellable microspheres, *much less* swellable microspheres comprising a high water absorbing polymer, and Applicants submit that swellable microspheres comprising a high water absorbing polymer are not obvious variants of those used in the methods of the '028 patent.

Thus, for at least these reasons, Applicants submit that the claimed invention is not obvious over the '028 patent. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**B. U.S. Patent No. 6,660,301**

The claims of the '301 patent recite methods and kits for dermal augmentation; whereas the claims of the present invention recite compositions for tissue bulking. The Examiner opines that it would have been obvious to make a composition as presently claimed and use it in the claimed methods and kits of the '301 patent (Office Action dated September 19, 2005).

As discussed above, the Examiner has previously restricted claims in the present case to 3 "distinct" groups: Group I drawn to compositions (claims 1-20), Group II drawn to methods (claims 21-46), and Group III drawn to kits (claims 47-51) (Office Action dated June 18, 2002). While Applicants traversed this rejection (Reply dated December 19, 2002), the Examiner maintained the Restriction Requirement, stating that "a kit is not related to a composition or a method, and the search of a method of use does not encompass a search for a compositions with specific constituents" (Office Action dated February 12, 2003, page 2).

Thus, by the Examiner's reasoning above, claims directed to a method of using a composition are patentably distinct from claims directed to a composition and/or a kit.

Moreover, the claims of the '301 patent generally recite "elastic" microspheres. With

respect to the term "elastic," the '301 patent specification states:

> "Elastic" microparticles or microspheres refers to microparticles or microspheres comprise polymers that have elastic properties. Specific to the present invention, elastic microspheres means particles that are flexible enough so that they can be easily injected through needles of 18 gauge or smaller, yet the microspheres are not fragile so that they are not broken during the process of injection.

('301 patent, Col. 8, lines 28-34).

In contrast, the claims of the present application recite "swellable" microspheres comprising a "high water absorbing polymer." As those skilled in the art are aware, not all "elastic" microparticles are "swellable" or comprise a "high water absorbing polymer," as recited in independent claim 1.

None of the claims of the '301 patent recite *any* composition comprising swellable microspheres, *much less* swellable microspheres comprising a high water absorbing polymer, and Applicants submit that swellable microspheres comprising a high water absorbing polymer are not obvious variants of those used in the methods of the '301 patent.

Thus, for at least these reasons, Applicants submit that the claimed invention is not obvious over the '301 patent. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**C. U.S. Patent No. 6,790,456**

The claims of the '456 patent recite compositions, methods and kits for dermal augmentation; whereas the claims of the present invention recite compositions for tissue bulking.

The claims of the '456 patent also recite that the microspheres are injectable through needles of about 30 gauge or smaller. In contrast, the present claims recite that the microspheres are injectable through needles of about 18-26 gauge or smaller. While it is true

that the microspheres of the '456 patent would be injectable through the larger size needles presently claimed, as acknowledged by the examiner, the larger 18-26 gauge needle size is not obvious variation of 30 gauge needles. Dermal augmentation is a method of "puffing up" skin wrinkles or other skin contour deficiencies, such as acne scars and, as such, smaller needles would be preferred to prevent, *e.g.*, pain and scarring from larger bore needles. In contrast, the present invention is directed to compositions and methods of physical bulking of tissue, such as, the lower esophageal sphincter, diaphragm, vocal cord tissues, and other non-dermal tissue, in which larger needle sizes are preferred. In other words, the different needle sizes are recited in the claims for quite different uses, thus making each composition suitable for one use (*e.g.*, tissue bulking), but not the other (*e.g.*, dermal augmentation).

While the Applicants do not agree with the Examiner that the compositions claims are not patentably distinct over those of the '456 patent, solely in an effort to advance prosecution of this application, Applicants submit herewith a Terminal Disclaimer disclaiming the portion of the patent term that extends beyond the '456 patent.

Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

## II. Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-4, 7, 8, 11-20 and 52 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement (Office Action dated September 19, 2005, pages 3-6).

The Examiner opines that the "specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation" (*Id.* at page 4). The Examiner alleges that :

> the claims herein [*sic* are] merely defined by various functions and without any limitation as to the materials employed therein. The claims broadly cover any composition that meet those functional

> limitations. In order to meet such limitation, a skilled artisan need [*sic*] to find a suitable materials [*sic*] with a suitable method to make such a composition. The application provides only one particular type of polymer, *i.e.*, polyacrylate, with a specific method of making such polymer so that spherical polymeric particle [*sic*] are produced in proper size.
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> * * *
>
> In the instant case, only a limited number of substantial spherical particle examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of polymers required, and method of making the particles from the polymer.

(*Id.* at page 5).

As the Examiner is aware, the number and variety of examples is irrelevant if the disclosure is "enabling" and sets forth the "best mode contemplated." *In re Borkowski,* 442 F2d 904 (CCPA 1970) (emphasis added). Further, M.P.E.P § 2164.01 states that 35 U.S.C. § 112, first paragraph, "has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation." The same section further states that "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation."

Applicants submit that one of ordinary skill in the art would know how to make and use the claimed injectable compositions without undue experimentation. For instance, the specification provides at least four examples of how to prepare microspheres that can be used in the claimed injectable compositions (see Examples 1-4). The preparation of the injectable compositions comprising the microspheres is described, *e.g.*, at page 17, line 16 - page 19, line 27) and Example 20. The methods described in the specification for preparing microspheres (*e.g.*, Examples 1-4) could be adapted by those skilled in the polymer art to prepare other hydrophilic polymeric microspheres that can be used in the claimed injectable compositions, without undue experimentation. Thus, using the knowledge of those skilled in

the art, together with the guidance provided by the specification, Applicants submit that one skilled in the art could make and use the invention without undue experimentation.

However, solely in an effort to advance prosecution of this application, Applicants have amended claim 1 to recite that the microspheres comprise a high water absorbing polymer selected from the group consisting of acrylic polymers, acrylamide polymers, vinyl alcohol polymers, acrylate polymers, sodium acrylate polymers, copolymers thereof, and combinations thereof.

Thus, Applicants submit that the claim 1, as amended herein, complies with all the requirements of 35 U.S.C. § 112, first paragraph. Similarly, claims 2-4, 7, 8, 11-20 and 52 (as well as new claim 53), which depend directly or indirectly on independent claim 1 and thus contain all the limitations thereof, also comply with the requirements of 35 U.S.C. § 112, first paragraph.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

## III. Rejection Under 35 U.S.C. § 102(b)

Claims 1-4, 7, 8, 11-20 and 52 have been rejected under 35 U.S.C. § 102 as allegedly being anticipated by Boschetti *et al.* (U.S. Patent No. 5,635,215) (Office Action dated September 19, 2005, pages 6-7).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that Boschetti "teaches the spherical particles herein and suspension [*sic*] composition comprising the same used for injection" (Office Action dated September 19, 2005, page 6).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal*

*Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

It is true that Boschetti *et al.* generally teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization (see, *e.g.*, Examples 1-21). However, nowhere does Boschetti *et al.* disclose swellable microspheres, *much less* a swellable microsphere comprising a high water absorbing polymer, as recited in independent claim 1. As those skilled in the art are aware, not all hydrophilic acrylic polymers are swellable and/or high water absorbing polymers.

For at least these reasons, Applicants respectfully submit that each of claims 1-4, 7, 8, 11-20 and 52-55 is novel over Boschetti *et al.* According reconsideration and withdrawal of this ground of rejection is respectfully requested.

## IV. Rejection Under 35 U.S.C. § 103

Claims 1-4, 7, 8, 11-20 and 52 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Boschetti *et al.* (U.S. Patent No. 5,635,215) (Office Action dated September 19, 2005, pages 7-8).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that Boschetti "teaches the spherical particles herein and suspension [*sic*] composition comprising the same used for injection" (Office Action dated September 19, 2005, page 7). The Examiner also opines that "it would have been prima facie obvious to a person of ordinary skill in the art...to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method" (*Id.* at page 8).

However, while it is true that Boschetti *et al.* generally teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization (see, *e.g.*, Examples 1-21), the reference does not teach or make obvious the claimed invention. *See, e.g., Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (Bd. Pat. App. & Int'f 1992) (prior art which provides only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it does not render the invention unpatentably obvious).

Nowhere does Boschetti disclose swellable microspheres...much less swellable microspheres comprising a high water absorbing polymer, as recited in independent claim 1. As those skilled in the art are aware, not all hydrophilic, acrylic polymers are swellable and/or high water absorbing. Moreover, as discussed throughout the specification, swellable microspheres comprising a high water absorbing polymer are advantageous, *inter alia*, due to the ability to control the size and degree of swelling, such as before and/or after injection into the patient (see, *e.g.*, page 12, lines 18-23; page 13, line 3 - page 14, line 7).

Thus, Applicants submit that Boschetti does not render any of 1-4, 7, 8, 11-20 and 52-55 According reconsideration and withdrawal of this ground of rejection is respectfully requested.

## V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that this application is now in condition for immediate allowance. If the Examiner disagrees, Applicants respectfully request that the Examiner call the undersigned at the number listed below.

A Petition for a One (1) Month Extension of Time is submitted herewith, with provisions for the required fee, which extends the response period from December 19, 2005 to January 19, 2006. The Petition further authorizes the PTO to charge the one month extension fee of $60 to Jones Day Deposit Account No. 50-3013, which reflects Applicant's

Small Entity Status. A Terminal Disclaimer and Terminal Disclaimer Fee Sheet is also submitted herewith, which authorizes the PTO to charge the processing fee of $65 to the same Deposit Account. Applicants believe no other fees are due in connection with this response. However, if there are any other fees due, please charge them to Deposit Account 50-3013. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above or in the Petition filed concurrently herewith, such an extension is requested and the fee should be charged to our Deposit Account. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,

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